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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,765	05/13/2005	Stefan Golz	Le A 35 838 (004974.01073	9673

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
07/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/508,765	GOLZ ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,27,28 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,27,28 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/09/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/09/2008 has been entered.

Claims 2, 27, 28, and 32-36 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejection of claims 2, 27, 28, and 32 under 35 U.S.C. 112, second paragraph for reciting the term "FPRL2" is withdrawn in view of the amended claim 2, from which claims 27, 28, and 32 depend.

Information Disclosure Statement

The information disclosure statement filed on 05/09/2008 has been considered by the examiner and a signed copy has been attached to this office action.

Claim Rejections under 35 U.S.C. § 101

(i). 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(ii). Claims 2, 27, 28, and 32-36 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

Claims 2, 27, 28, and 32-36 are drawn to a method of screening for therapeutic agent useful in the treatment of heart failure comprising determining the activity of a FPRL2 polypeptide in the presence or absence of a test compound. Since the invention is drawn to a method of screening for therapeutic agent useful in the treatment of heart failure, the determination of the utility of the claimed invention is based upon whether the agent identified by the method is useful in the treatment of heart failure.

The specification discloses the FPRL2 polypeptide of SEQ ID NO: 2 (middle of page 4), and the distribution of FPRL2 mRNA in cells and tissues (Example 2, Table 1). The specification asserts that the invention relates to methods of screening for a therapeutic agent for the treatment of a long list of diseases, including cardiovascular diseases (last paragraph of page 4). At page 55 under the section of cardiovascular disorders, the specification discloses, among numerous cardiovascular disorders, that heart failure is defined as a pathophysiological state in which an abnormality of cardiac function is responsible for the failure of the heart to pump blood at a rate commensurate with the

requirement of the metabolizing tissue. It includes all forms of pumping failure such as high-output and low-put, acute and chronic, right-sided or left-sided, systolic or diastolic, independent of the underlying cause. However, there is no evidence on the record showing that there is causative link between the FPRL2 polypeptide of SEQ ID NO: 2 and a particular heart failure. The prior art teaches FPRL2 is a chemotactic receptor transducing signals in myeloid cells (Christophe et al., J. Biol. Chem. 276:21585-21593, 2001). Clearly, further research would be required to determine whether there is a causative link between the FPRL2 polypeptide and heart failure and whether a compound identified in the claimed method is useful in treating heart failure. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Accordingly, the claimed invention is not supported by a specific and substantial asserted utility.

Claim Rejections under 35 USC § 112, 1st Paragraph

Claims 2, 27, 28, and 32-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Applicants' argument

Applicants argue that combined with the high expression of FPRL2 in tissues disclosed in the specification (page 86, Table 1), the skilled artisan can be readily use the claimed screening methods to screen for therapeutic agents which regulate FPRL2 activity and which therefore could be used to treat heart failure. Applicants argue that identified inhibitors can be used to treat high-output heart failure and identified activators can be used to treat low-output heart failure. Applicants also argue that causative link to a heart failure is not required for a particular drug target to useful for the treating heart failure.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the assertion that the FRPL2 protein can be used in screening methods to identify potential therapeutic compounds for heart failure does not represent a specific and substantial utility because the specification does not identify a particular disease, such as heart failure, that can be treated; instead, the specification lists a long list of diseases (last paragraph of page 4 and 53-60). Even hear failure further comprises many different pathophysiological states with distinct pathological features (page 55).

Secondly, the mRNA quantification shows expression of FPRL2 in various human tissues, including breast and lung tumors ((Table 1 on page 88). It is noted that in the whole heart, the relative expression of FPRL2 is quite low, with a value of 25. Thus, Tale 1 does not show a predominant expression of FPRL2 polypeptide in heart or in

cardiomyocytes.

Thirdly, the prior art teaches FPRL2 is expressed on monocytes and is a chemotactic receptor (Christophe et al., J. Biol. Chem. 276:21585-21593, 2001; in particular page 21586, the 2nd paragraph of left column). Neither prior art nor the instant disclosure establishes that the FPRL2 polypeptide modulates myocardial contractiility or an altered activity of the FPRL2 polypeptide leads to heart failure.

Furthermore, in order to screen for a therapeutic agent that is useful in treatment of heart failure, a causative link between the FPRL2 polypeptide and a specific type of heart failure is required. Without such knowledge, one of skilled in the art would not know what type of therapeutic compound, an agonist or antagonist of FRPL2, is useful in treating heart failure.

Clearly, further research would be required to determine whether there is a causative link between the FPRL2 polypeptide and a specific heart failure and whether an agonist or an antagonist of the FRPL2 screened by the instantly claimed method can be used to treat heart failure. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Claim Rejections under 35 USC § 112, 2nd paragraph

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 2, 27, 28, and 32-36 are indefinite because they recite "the activity of a formyl peptide receptor-like 2". Neither the specification nor the claims defines the term unambiguously, rendering the claim indefinite. Claims 27, 28, and 32-36 are rejected as dependent claims from claim 2.

Claim Objections for Minor Informalities

Claim 27 is objected to because it depends from canceled claim 26. Appropriate correction is required.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
July 16, 2008